

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

CITY OF ROCKFORD

on behalf of itself and
all others similarly situated,

Plaintiff,

v.

**MALLINCKRODT ARD, INC.,
formally known as QUESTCOR
PHARMACEUTICALS, INC.;
MALLINCKRODT PLC;
and UNITED BIOSOURCE
CORPORATION**

Defendants.

Civil Action No.:

**COMPLAINT –
CLASS ACTION**

JURY TRIAL DEMANDED

TABLE OF CONTENTS

	<u>Page</u>
NATURE OF THE CASE	1
JURISDICTION AND VENUE	3
PLAINTIFF.....	5
DEFENDANTS	5
FACTUAL BACKGROUND.....	6
RELEVANT MARKETS AND MONOPOLY POWER	10
CLASS ACTION ALLEGATIONS	25
<i>Numerosity</i>	26
<i>Typicality</i>	26
<i>Adequacy of Representation</i>	27
<i>Commonality</i>	27
<i>Predominance</i>	28
<i>Superiority</i>	29
COUNT I	
CITY OF ROCKFORD v. MALLINCKRODT MONOPOLIZATION OF THE ACTH DRUG MARKET.....	29
COUNT II	
CITY OF ROCKFORD v. DEFENDANTS ANTI-COMPETITIVE AGREEMENTS IN UNREASONABLE RESTRAINT OF TRADE (15 U.S.C. § 1).....	31
COUNT III	
CITY OF ROCKFORD v. DEFENDANTS Violation of 18 U.S.C. § 1962(c).....	32
COUNT IV	36
CITY OF ROCKFORD v. DEFENDANTS	36
Violation of 18 U.S.C. § 1962(a).....	36
COUNT V	
CITY OF ROCKFORD v. DEFENDANTS (18 U.S.C. § 1962(D)).....	37
COUNT VI	
CITY OF ROCKFORD v. DEFENDANTS VIOLATION OF ILLINOIS' CONSUMER FRAUD AND DECEPTIVE PRACTICES ACT (815 ILCS 505/1 <i>et. seq.</i>).....	38

COUNT VII	
CITY OF ROCKFORD v. DEFENDANTS UNJUST ENRICHMENT	41
COUNT VIII	
CITY OF ROCKFORD v. MALLINCKRODT, UBC, AND UNNAMED CO-CONSPIRATOR DEFENDANTS.....	42
CONSPIRACY	42
PRAYER FOR RELIEF	44
JURY DEMAND	45

CLASS ACTION COMPLAINT

The City of Rockford (“the City” or “Rockford”) on its own behalf, and on behalf of the Class described below, alleges as follows:

NATURE OF THE CASE

1. Plaintiff, the City of Rockford, brings this action on its own behalf and on behalf of all other government payors, as well as self-funded private payors similarly situated, to challenge an anti-competitive, unfair and deceptive scheme by Defendants, Mallinckrodt ARD Inc., formally known as Questcor Pharmaceuticals, Inc. (“Questcor”) and its parent company, Mallinckrodt plc (collectively “Mallinckrodt”), along with Mallinckrodt’s self-described agent, United BioSource Corporation (“UBC”), to enhance and maintain Mallinckrodt’s monopoly power in the U.S. market for adrenocorticotrophic hormone (ACTH) drugs in violation of the U.S. antitrust laws.

2. Mallinckrodt manufactures, markets, distributes and sells Acthar, NDC No. 63004871001. Acthar is the only therapeutic ACTH product sold in the United States. Mallinckrodt is the sole provider in the U.S. of approved ACTH drugs. Thus, Mallinckrodt is a monopolist.

3. Acthar is a “specialty pharmaceutical”. It is neither sold in retail pharmacies, nor distributed through wholesalers to retail pharmacies. Instead, it is distributed through “specialty pharmacies.” Distinguishing features of specialty pharmaceuticals like Acthar, beyond their high prices, are their important therapeutic effects, their complicated storage and use requirements, and their relatively small share of the market of total drugs sold in relation to their relatively large share of overall drug expenditures.

4. As discussed below, in 2007, Questcor changed its distribution of Acthar,

vertically integrating its sales and distribution through one exclusive distributor, Curascript. This was the beginning of Mallinckrodt's monopolistic conduct and unlawful scheme to inflate the prices of Acthar.

5. Questcor acquired the rights to Acthar from Aventis in 2001 for just \$100,000. At the time, Acthar sold for just \$40 per vial (or less). Between 2001 and early 2007, Questcor raised the price over time to \$2,062.79 per vial.

6. But in July 2007, Questcor embarked on a new strategy and business model: to limit distribution to one specialty pharmacy distributor (Curascript) to enhance its monopoly power and to increase the price of Acthar more than tenfold, to \$23,000 per vial. They also chose to focus on one primary indication, infantile spasms ("IS"), for which the drug was not yet approved by the FDA, but for which the potential to raise prices unchecked by competition was tremendous. As a result, the cost of a course of treatment (typically 4 to 5 injections) for one child suffering from IS was increased to more than what it cost Questcor to acquire the drug six years earlier.

7. Then in 2013, to protect its monopoly on Acthar and to maintain its high prices, Questcor paid nearly ten times what a competitor had offered to purchase Synacthen which was a synthetic version of Acthar and the only potentially competitive product in the market. (That competitor happened to be Retrophin, headed by the now-infamous Martin Shkreli.)

8. On January 18, 2017, the Federal Trade Commission ("FTC") announced that Questcor and its parent Mallinckrodt agreed to pay \$100 million to settle FTC charges that Questcor and Mallinckrodt violated antitrust laws when Questcor acquired the rights to Synacthen from Novartis in 2013.

9. In a complaint filed the same day as its stipulated settlement, the FTC alleged that

Questcor illegally acquired the U.S. rights to Synacthen. The acquisition stifled competition by preventing any other company (including Retrophin) from using the Synacthen rights to develop a U.S.-based competitor to Acthar, thereby preserving Questcor's monopoly and allowing it to maintain its extremely high prices for Acthar.

10. According to FTC Chairwoman Edith Ramirez, "Questcor took advantage of its monopoly to repeatedly raise the prices of Acthar, from \$40 in 2001 (when it acquired the rights to sell Acthar for \$100,000) to more than \$34,000 per vial today – an 85,000 percent increase."

11. The brunt of these monopoly prices was borne by self-funded payors , like Rockford, located throughout the country, whose employees and beneficiaries had children afflicted with IS and were at the mercy of Mallinckrodt.

12. The City spent \$489,057.84 for just 9 administrations of Acthar given to 2 patients at a gross cost per vial of \$54,339.76. As a result, Rockford, and other members of the Class paid the monopoly prices charged by the Defendants for Acthar.

13. For this reason, the City of Rockford brings this case on behalf of itself and a Class of all similarly-situated purchasers of ACTH drugs, to obtain declaratory and injunctive relief, and to recover overcharges resulting from the illegal monopolization scheme, RICO violations, and unlawful conduct alleged herein. Alternatively, the City seeks declaratory and injunctive relief, damages, and other appropriate relief under the statutory consumer fraud laws and the common law of Illinois and other states where similarly-situated purchasers of ACTH drugs may be found, as described below.

JURISDICTION AND VENUE

14. The City brings this action pursuant to sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15(a) and 26, to recover treble damages, costs of suit, and reasonable attorneys' fees

for the Defendants' violations of sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2.

This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337(a).

15. This Court also has subject matter jurisdiction over this action pursuant to the Class Action Fairness Act of 2005, 28 U.S.C. § 1332(d), because the City and members of the Class are diverse from the Defendants and over two-thirds of the Class is situate outside of Illinois. Due to the exorbitant prices charged by Defendants for Acthar to the Class, the aggregate amount in controversy exceeds \$5,000,000.

16. Further, the Court has supplemental jurisdiction over the City's state law statutory and common law claims pursuant to 28 U.S.C. § 1337 because these claims arise from the same occurrence or transaction and are related to the City's Sherman Act claims as to form part of the same controversy.

17. This Court has personal jurisdiction over the parties because the Defendants conduct substantial business in this State, have had systematic and continuous contacts with this State, and have agents and representatives that can be found in this State.

18. The Court has jurisdiction over Mallinckrodt and UBC because they have had sufficient minimum contacts with and/or have purposefully availed themselves of the laws and markets of the State of Illinois through, among other things, their conspiratorial communications between themselves and with others (including telephonic and electronic communications) and their distribution, marketing and sales of Acthar to the residents of Illinois.

19. Venue is proper in this District pursuant to section 12 of the Clayton Act, 15 U.S.C. § 22, because the City is situated in this District, and the Defendants transact business in this District. Venue is also proper because a substantial part of the events giving rise to the City's claims occurred in this District. Defendants engaged in substantial conduct relevant to the

claims of the City and the Class, and caused harm to members of the Class in this District. Venue is also proper pursuant to 28 U.S.C. §1391.

20. Acthar is sold in interstate commerce and the unlawful activities alleged in this Complaint have occurred in, and have had a substantial effect upon, interstate commerce.

THE PARTIES

PLAINTIFF

21. The City of Rockford, Illinois employs over a thousand individuals in the service of its citizens. Two such employees have children who had a medical condition, for which Acthar was indicated as a treatment option. The City, which pays the health care benefits of its employees, including prescription drugs, paid for these administrations of Acthar. The sum total of these 9 prescriptions (14 administrations) was \$489,057.84. The City paid \$488,787.84, while the employees paid \$270.00 (which was a \$30 co-pay for each of the 9 prescriptions).

DEFENDANTS

22. Questcor Pharmaceuticals, Inc. (“Questcor”) was acquired by Mallinckrodt on August 14, 2014 for \$5.9 billion. Following the acquisition, Questcor became a wholly-owned subsidiary of Mallinckrodt and its name was changed to Mallinckrodt ARD Inc. Mallinckrodt ARD Inc. is a biopharmaceutical company incorporated in California, with offices located at 675 McDonnell Blvd, Hazelwood, Missouri 63042. Mallinckrodt ARD Inc. now has locations in Hampton, New Jersey and Bedminster, New Jersey. For clarity, this entity is herein referred to as “Questcor”.

23. At the time of the acquisition, Questcor’s only product sold in the United States was Acthar. As of the date of this Class Action Complaint, Questcor continues to manufacture, distribute and sell Acthar directly to patients, through a program known as the “Acthar Support

and Access Program” (“ASAP”).

24. Defendant, Mallinckrodt plc (“Mallinckrodt plc”), is an Irish public limited company, with its corporate headquarters in Staines-upon-Thames, United Kingdom. Its principal executive offices are located at 3 Lotus Park, the Causeway, Staines-upon-Thames, Surrey, TW18 3 AG.

25. Mallinckrodt plc and Questcor are collectively referred to as “Mallinckrodt”.

26. Defendant United BioSource Corporation (“UBC”) is a Delaware corporation with its corporate headquarters at 920 Harvest Drive, Blue Bell, Pennsylvania 19422. UBC is a wholly-owned subsidiary of Express Scripts Holding Company (“Express Scripts”), a Delaware Corporation, with its principle executive offices located at One Express Way, Saint Louis, Missouri 63121.

27. UBC is Mallinckrodt’s self-described “agent” which Mallinckrodt employs exclusively to operate the ASAP and to manage the distribution, sales and reimbursement of Acthar directly to patients.

28. Mallinckrodt plc, Questcor and UBC are collectively referred to herein as “Defendants”, as appropriate.

29. The Defendants’ acts alleged in this Complaint to have been done by each of the Defendants were authorized, ordered, done and/or ratified by their respective officers, directors, agents, employees or representatives while engaged in the management, direction, control or transaction of their respective business affairs.

FACTUAL BACKGROUND

30. “I have a Cadillac in my refrigerator.” That is how one Acthar patient named Sharon Keller described an unused 5-ml vial of the medication sitting in her kitchen refrigerator.

31. The tale of how a 65 year-old brand medication could rise in price from \$40 per vial in 2001, to over \$35,000 per vial by 2015, is a story of perhaps the most egregious monopolistic conduct and unfair trade practice in U.S. history.

History of Acthar Development, Pricing, Marketing and Distribution

32. H.P. Acthar Gel (“Acthar”) was approved by the Food and Drug Administration (“FDA”) in 1952 for over 50 indications. However, by 2014, that list of indications decreased to 19.

33. Acthar is adrenocorticotropic hormone (“ACTH”), which causes the body to produce cortisone and other steroid hormones. Two Mayo Clinic researchers, Drs. Philip Hench and Edward Kendall, developed the treatment, which won them the Nobel Prize for medicine at the time it was developed.

34. For the majority of the drug’s lifespan, however, generic corticosteroids, such as prednisone, effectively treated the majority of the indications for which Acthar was approved, limiting the market for Acthar to treating infantile spasms (“IS”) as an “off-label” treatment, because Acthar was not approved to treat IS. Consequently, because of the limited, off-label market for Acthar, by 2001, the drug was priced at \$40 per vial and accounted for less than a million dollars of revenue for Aventis Pharmaceuticals, Inc. (“Aventis”), the then-owner.

35. In 2001, Questcor acquired Acthar from Aventis for \$100,000 and limited royalties. As stated above, at acquisition, Acthar’s price was just \$40 per vial.

36. Immediately following the acquisition, however, Questcor raised Acthar’s price to \$700 per vial. Questcor then sought approval from the FDA for Acthar to be indicated for the treatment of IS by filing a supplemental New Drug Application (“sNDA”). It sought to have the drug declared an “orphan drug” which would grant Questcor a period of exclusivity. It received

FDA approval in 2010, along with 7 years of exclusivity.

37. From the time it sought FDA approval for the treatment of IS, Questcor raised the price of Acthar to over \$20,000.

38. Questcor claimed that these exorbitant price increases were in response to demand. But its Chief Executive Officer, Don Bailey, acknowledged in 2009 that “we only have about 800 patients a year. It’s a very, very small – tiny – market.” Consequently, the limited use of the product did not justify an over 58,000% price increase from acquisition until 2009.

39. Since the Acthar market for the treatment of IS was limited, Questcor sought to expand its use. By 2012, Acthar was prescribed for Medicare recipients 3,387 times. To Medicare alone, this represented a cost of \$141,500,000 in 2012.

40. Quantified another way, Dr. William Shaffer, a neurologist in Greeley, Colorado who was the highest prescriber of Acthar in 2012, wrote only 78 prescriptions for the drug, but the prescribed Acthar cost Medicare \$4,000,000.

41. Acthar represented 98% or more of Questcor’s sales and revenue from sales since 2007. Its manipulation of the market has resulted in a 266% increase in revenue year-over-year from 2011 to 2013. Total net sales for Questcor in 2011 were \$218.2 million, \$509.3 million in 2012, and \$798.9 million in 2013. In each of those years, Acthar represented at least 95% of Questcor’s net sales – over \$1.45 billion in revenue.

42. In the words of CEO Don Bailey “Questcor is basically a single-product company.” But, by flexing its monopoly power, Questcor has been able to raise Acthar prices and increase revenue from Acthar in a “tiny market” from less than \$1 million for fiscal 2001 to \$799 million for fiscal 2013 - a nearly 80,000% increase.

Acthar Distribution

43. Acthar is distributed directly to patients through essentially a consignment arrangement with a single distributor managed by Mallinckrodt's agent UBC.

44. Mallinckrodt operates an "Acthar Support & Access Program" known as "ASAP" that "ensure[s] efficient, seamless service." Under ASAP, physicians refer patients to Mallinckrodt who arranges for Acthar to be delivered directly to the patient.

45. Mallinckrodt engages Defendant UBC as its exclusive agent to coordinate all aspects of the drug prescription/authorization, distribution, and payment.

46. Once the patient (or their physician) contacts Mallinckrodt for a prescription of Acthar, Mallinckrodt and UBC, through ASAP, confirm the patient's insurance coverage or other source of payment, and then arrange for Acthar to be delivered directly to the patient.

47. The process begins with the physician and patient filling out a form provided by Mallinckrodt, (the "Acthar Start Form"). *See Exhibit "A" hereto.* The Acthar Start Form consists of 3 sections: (1) a form requiring signature by the "HCP" (or health care professional); (2) a patient authorization requiring signature by the "patient or legal representative"; and (3) an information form concerning Acthar indications and usage. The required signature of the patient ostensibly authorizes "Mallinckrodt and its agents" to do a number of things in relation to the prescription of Acthar. It further authorizes Mallinckrodt and its agents, "including Mallinckrodt reimbursement support personnel and United BioSource Corporation ("UBC") or any other operator of the Acthar Support Access Program on behalf of Mallinckrodt (collectively, 'Designated Parties'))" to provide Acthar and receive payment, among other things.

48. Specifically, the patient authorizes Mallinckrodt, UBC "or any other operator" of ASAP on behalf of Mallinckrodt, "collectively ('Designated Parties') to provide certain services to [the patient], including reimbursement and coverage support, patient assistance and access

programs, medication shipment tracking, and home injecting training.” In other words, the patient must directly authorize Mallinckrodt and its agents to direct all aspects of Acthar’s distribution and payment prior to obtaining the medication.

49. Similarly, the physician must “authorize United BioSource Corporation (“UBC”), the current operator of the Acthar Support and Access Program (“Program”), and other designated operators of the program, to perform a preliminary assessment of benefit verification for this patient...”. The physician also “agree(s) that the designated specialty pharmacy receive this prescription via a designated third party, the Program and that no additional confirmation of receipt of prescription is required by the designated specialty pharmacy.”

50. CuraScript SD (“Curascript”) is a specialty pharmacy distributor, and wholly-owned subsidiary of Express Scripts, the same parent of Defendant UBC. Curascript’s corporate headquarters are located at 255 Technology Park, Lake Mary, Florida 32746. This is the same address patients are required to mail any revocation of the broad authorization, granted by the Acthar Start Form (*see Exhibit “A”*). Thus, Curascript as the designated specialty pharmacy, is a “Designated Party”, and is an operator of ASAP with Mallinckrodt.

51. As described above, in 2007, Questcor decided to limit its distribution of Acthar to just one exclusive specialty pharmacy distributor, to maintain its monopoly prices and profits. Mallinckrodt contracted with Curascript to be its exclusive specialty pharmacy distributor of Acthar throughout the country. Mallinckrodt also engaged UBC as its agent to coordinate the exclusive distribution of Acthar directly to the children of City employees and the children of other municipal employees and self funded plan beneficiaries throughout the country, through Curascript. Both entities are “operators” of ASAP along with Mallinckrodt.

RELEVANT MARKETS AND MONOPOLY POWER

52. In its 2017 complaint, the FTC alleged that Mallinckrodt exercised, and continues to exercise, monopoly power in the United States in the sale of Acthar. *See* Complaint for Injunctive Relief and Other Equitable Relief (“FTC Complaint”) at Exhibit “B” hereto. (To the extent relevant to Plaintiff’s Complaint, the averments of antitrust conduct interposed by the FTC are incorporated by reference herein.)

53. The supracompetitive and exorbitant prices that Mallinckrodt charges for Acthar and its limitations on distribution through an exclusive distribution arrangement are direct evidence of Mallinckrodt’s monopoly power. Mallinckrodt’s monopoly power is also established by indirect evidence, which shows that Acthar holds a dominant share of the relevant market for ACTH drugs in the United States. That market is and has been characterized by significant barriers to entry.

54. The relevant product market is the sale of ACTH drugs, dominated by just one product, Acthar.

55. There are no medical or reasonably available substitutes for Acthar. The only potential substitute was Synacthen, which Mallinckrodt purchased the rights to from Novartis in 2013, only to shelve the product rather than seek to bring it to market in the United States.

56. The FTC alleged that such purchases “extinguished a nascent competitive threat to [Mallinckrodt’s] monopoly.” FTC Complaint, ¶ 1, at Exhibit “B” hereto.

57. At all relevant times, Mallinckrodt possessed monopoly power—the ability to profitably raise price significantly above competitive levels without losing significant sales -- in the relevant product market. None of the vast price increases taken by Mallinckrodt between 2007 and the present have caused a significant loss of sales. To the contrary, Mallinckrodt’s sales have increased during that time.

58. Mallinckrodt repeatedly and profitably raised Acthar's price from the time it acquired the product for \$100,000. From acquisition until August 27, 2007, Mallinckrodt increased the price of Acthar from \$40 to \$1,650 per vial – a 4,025% increase. But, on that date, it exponentially inflated the price 1,310%, from \$1,650 to \$23,269 per vial. Following that exorbitant price increase, Mallinckrodt took an additional eight (8) price increases, pushing the price up to a 2015 price of \$35,279 per vial. From 2011 to 2015, Acthar net sales grew from \$218 million to more than \$1 billion.

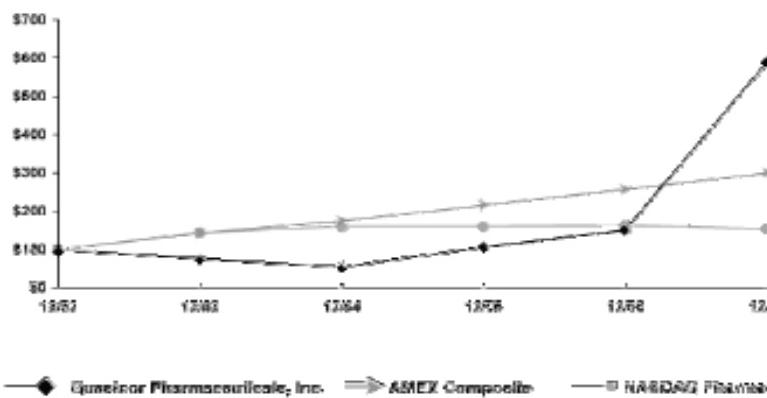
59. Mallinckrodt has encountered no competitive constraints on its ability to repeatedly increase Acthar's price and, by extension, its revenue and profit margins. Mallinckrodt does not set the price of Acthar in reference to the price of any of the other drugs that are prescribed to treat the same indications that Acthar treats. Acthar is priced significantly higher than non-ACTH drugs used to treat the same indications.

60. Indeed, one Mallinckrodt executive commented that the price for Acthar “was chosen by looking at the prices of other specialty drugs and estimating how much insurers and employers would be willing to bear.” Mallinckrodt took “some comfort that the strategy would work, and physicians would continue to use the drug, and payers would continue to pay.” In fact, according to Mallinckrodt, “reality was better than expected.”

61. In its Annual Report on Form 10-K for the Fiscal Year ended December 31, 2007, Questcor illustrated the effect of its monopolization strategy on its “5 Year Cumulative Total Return”, illustrating a 290% return between 2006 and 2007 as follows:

Comparison of 5 Year Cumulative Total Return*
Among Questcor Pharmaceuticals, Inc.,
the AMEX Composite Index
and the Nasdaq Pharmaceutical Index

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Questcor Pharmaceuticals, Inc., The AMEX Composite Index
And The NASDAQ Pharmaceutical Index



—●— Questcor Pharmaceuticals, Inc. —> AMEX Composite —□— NASDAQ Pharmaceutical

	Cumulative Total Return*					
	12/02	12/03	12/04	12/05	12/06	12/07
QUESTCOR PHARMACEUTICALS, INC.	100.00	75.51	54.08	106.13	151.02	588.78
AMEX COMPOSITE INDEX	100.00	143.18	175.20	213.26	257.04	299.37
NASDAQ PHARMACEUTICAL INDEX	100.00	144.89	160.46	160.65	163.42	154.46

* \$100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ended December 31.

This stock performance graph shall not be deemed "filed" for purposes of Section 16 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

62. The relevant geographic market is the United States. FDA approval is required to market pharmaceuticals to U.S. consumers. As a result, drugs sold outside of the United States are not viable competitive alternatives for U.S. consumers, even in the event of a significant price increase for ACTH drugs available in the United States.

63. Acthar has a 100% share of the market for ACTH drugs in the United States. No other ACTH drug is FDA-approved for therapeutic use.

64. The United States ACTH market is characterized by high barriers to entry. Developing a long-acting, depot-injection formulation of a drug product containing ACTH (natural or synthetic) that is stable, safe, and effective would require significant time, cost, and effort, with no guarantee of success. The requirements for entry include sourcing the active pharmaceutical ingredient, formulating a sustained-release depot-injection formulation, scaling

production to clinical scale, and successfully conducting clinical trials necessary for FDA approval. Mallinckrodt's CEO Don Bailey has assured investors that Acthar "has significant durability in the marketplace" because "it will be very difficult for this product to be replicated in any way [by] a generic."

65. CEO Don Bailey also claimed that one of the barriers to entry is the Acthar drug formulation. While Acthar is a biologic extraction of porcine pituitaries, Bailey claims, "[i]t's an undisclosed composition, so that's a trade secret." He also claims "[t]he manufacturing process is also a trade secret. It's complex, it's unique, and we own all elements of the manufacturing process. ...The composition of Acthar that comes out of the manufacturing process is tied to the process, so if you don't know the process you can't figure out what's actually in Acthar."

Mallinckrodt Engaged in Anticompetitive Conduct By Acquiring the Only Competitor Drug, Synacthen

66. Synacthen posed a threat to Mallinckrodt's ACTH drug monopoly, so Questcor intervened at the time when other firms were attempting to acquire the U.S. rights to Synacthen from Novartis. Questcor submitted a bid that included substantially more guaranteed money than the other bidders had offered, effectively ending the bidding process. By acquiring Synacthen, Questcor eliminated the possibility that another firm would develop it and compete against Acthar.

Synacthen Posed a Competitive Threat to Acthar

67. Synacthen constituted a nascent competitive threat to Questcor's ACTH drug monopoly, notwithstanding the uncertainty that Synacthen, a preclinical drug, would be approved by the FDA.

68. For years, Questcor viewed Synacthen as a significant potential competitive threat to its monopoly.

69. On information and belief, in 2006, when Questcor first decided to pursue an “orphan drug” (*i.e.*, high) pricing model for Acthar, it recognized the potential threat Synacthen posed to Acthar’s revenue growth.

70. Nevertheless, in 2007, it adopted and pursued its new marketing, sales and distribution strategy of consolidating Acthar distribution to just one distributor, Curascript, and streamlining its control over sales and distribution through the implementation of ASAP.

71. Then in 2009, Questcor approached Novartis about acquiring Synacthen. At that time, Questcor continued to view Synacthen as a possible future competitor, especially given the increasing prices Questcor was commanding for Acthar. Unsuccessful in that initial attempt, Questcor continued to monitor the competitive threat from Synacthen.

72. Then in 2012, Questcor again concluded that Synacthen posed a more immediate threat to Acthar if Synacthen was approved for sale in the United States.

73. By 2013, Questcor feared that if another company were to acquire Synacthen and obtain FDA approval, it could undermine its business model.

74. On information and belief, as long as Questcor believed no other firm was seeking to bring Synacthen to the United States, Questcor did not make further attempts to acquire it. Indeed, just months before Questcor began pursuing the acquisition of Synacthen, top Questcor officials questioned whether Synacthen would provide any affirmative value to Questcor.

Other Bidders Planned to Use Synacthen to Challenge Acthar’s Monopoly

75. Unbeknownst to Questcor at the time, Novartis decided in late 2011 to divest exclusive rights to seek FDA approval for Synacthen and commercialize it in the United States, along with the marketing rights for Synacthen in over thirty-five other countries where the drug was already approved and sold. Dozens of companies contacted Novartis and expressed interest

in acquiring Synacthen. Three firms proceeded through several rounds of negotiations with Novartis, submitted formal offers, and drafted near-final agreements.

76. On information and belief, each of the three firms planned to develop Synacthen for IS and to use Synacthen to compete directly with Acthar. With this indication, each firm expected to capture a significant share of the U.S. ACTH market from Questcor by pricing Synacthen below Acthar's prices. Having the requisite pharmaceutical expertise and financing, the three firms independently conducted due diligence, crafted business plans and regulatory approval strategies, and took other affirmative steps in furtherance of developing Synacthen for the U.S. ACTH market.

The Value of the Synacthen Assets

77. The Synacthen assets and related rights provide a proven formulation for a long-acting, depot-injection drug containing synthetic ACTH. The drug product manufactured using the Synacthen formulation has been safely and effectively used to treat patients suffering from IS and other conditions worldwide for decades. The Synacthen assets would therefore facilitate commercializing a synthetic ACTH therapy in the United States.

78. The asset package being sold by Novartis included valuable trade secrets, including technical documentation detailing both the precise formulation for the Synacthen drug product and the manufacturing process.

79. In possession of the Synacthen assets, a buyer would not need to create a synthetic ACTH drug formulation *de novo*, nor would it need to develop from scratch the manufacturing and testing protocols necessary for production of the drug product.

Questcor Disrupted the Synacthen Bidding Process

80. On information and belief, in October of 2012, Questcor learned that at least one

unidentified firm was attempting to acquire Synacthen from Novartis to develop it to compete with Questcor for the U.S. ACTH market. Questcor immediately reached out to Novartis, signed a confidentiality agreement with Novartis, and submitted a confidential offer for the purchase of Synacthen.

81. On information and belief, Novartis negotiated with the three alternative bidders in parallel with Questcor. By the spring of 2013, all three of the alternative bidders had submitted offers for Synacthen, with plans to develop and launch Synacthen in the United States in direct competition with Acthar. At the point where those negotiations left off, each company exchanged deal terms with Novartis and submitted formal offers. The offers by the three alternative bidders were comparable in value and structured similarly, and included an upfront payment, milestone payments upon FDA approval, and significant royalties on U.S. sales of Synacthen.

82. On information and belief, unlike the three alternative bidders, Questcor had only incomplete plans for Synacthen and conducted limited due diligence when it submitted its initial offer to Novartis.

83. One of the three alternative bidders was Retrophin, Inc, a Delaware corporation ("Retrophin"), headed by a now infamous Chief Executive Officer named Martin Shkreli ("Shkreli"). Retrophin ultimately prevailed in the bidding war with a bid of \$16 million.

84. However, on June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor and Novartis entered into a Licensing Agreement, Asset Purchase Agreement, and Supply Agreement (collectively, "the Agreements"). By the Agreements, Questcor gained the exclusive rights to develop, market, and sell Synacthen in the United States and over thirty-five other countries. Under the Agreements, Questcor is obligated to pay a

minimum of \$135 million, and likely will pay \$300 million to Novartis for Synacthen.

85. In other words, Questcor swept in at the eleventh hour to overpay—at least 8 times more than the market had determined—for the only immediate competitive threat to its monopoly for Acthar.

The Lawsuit Between Retrophin and Questcor for Questcor's Antitrust Violations

86. In January 2014, Retrophin sued Questcor for antitrust violations in the United States Federal District Court for the Central District of California. *See Retrophin, Inc., v. Questcor Pharmaceuticals, Inc.*, CV-14-00026-JLS (C.D.Cal) ("Retrophin Complaint") at Exhibit "C" hereto. (To the extent relevant to Plaintiff's Complaint, the averments of antitrust conduct interposed by Retrophin are incorporated by reference herein).

87. In the Retrophin Complaint, Retrophin claimed,

"[i]n June of 2013, plaintiff Retrophin was poised to challenge Questcor's monopoly. It had negotiated an agreement to purchase from Novartis AG ("Novartis"), the rights to sell in the US a product called Synacthen. ...

Retrophin planned to obtain FDA approval to sell Synacthen in the US and compete head to head against Questcor by dramatically undercutting Questcor's price for Acthar. It had negotiated and was ready to sign an agreement to purchase the US rights to Synacthen from Novartis. The signing was scheduled for June 11, 2013. The signing of the agreement was so imminent that a press release had been prepared to announce the deal.

On June 11, 2013, the day Retrophin was to sign its agreement with Novartis, Questcor swept in and acquired the rights to Synacthen. In doing so, it preserved and entrenched its ACTH monopoly in US and eliminated the competitive threat posed by Retrophin's acquisition of Synacthen. There was no procompetitive aspect of Questcor's acquisition of Synacthen.

Retrophin Complaint, ¶¶ 4-6, at Exhibit "C" hereto.

88. The federal government agreed with Retrophin's assessment, despite the fact it

subsequently criminally indicted Retrophin's CEO, Shkreli, for securities fraud charges, and despite the fact that Shkreli himself was accused of the same sort of price gouging conduct involving orphan drugs as Retrophin accused Questcor of doing. Indeed, Shkreli was accused of such conduct both while at Retrophin -- where he increased the cost of Thiola more than 2,000% -- and his successor company, Turing, where he increased the cost of Daraprim from \$13.50 per tablet to \$750.00 per tablet, more than 5,500%.

89. Nevertheless, the government, in its 2017 FTC complaint, mirrored Retrophin's 2014 allegations that Questcor engaged in anticompetitive conduct in violation of the antitrust laws. *See generally*, FTC Complaint at Exhibit "B".

90. Mallinckrodt chose to settle the government's case by payment of \$100 million, and a stipulated agreement to grant a license to develop Synacthen to treat IS to a licensee approved by the FTC.

91. Mallinckrodt also chose to settle the Retrophin lawsuit for \$15.5 million, slightly less than the \$16 million Retrophin bid to purchase Synacthen from Novartis.

Mallinckrodt's Acquisition of Synacthen Harmed Competition

92. Mallinckrodt's strategy to protect its monopoly power in the market for ACTH drugs was successful. But for Mallinckrodt's acquisition of Synacthen, one of the three alternative bidders, including Retrophin, would have acquired Synacthen and pursued its plan to develop Synacthen for IS to compete directly with Acthar at a lower price. With the acquisition of Synacthen, Mallinckrodt was able to thwart an imminent threat to its Acthar monopoly and thereby harmed competition.

93. Mallinckrodt claimed that it acquired Synacthen to develop it for new, non-Acthar indications, but given the similarities between the two drugs, any therapeutic indication that

Mallinckrodt was to pursue for Synacthen could easily have been pursued for Acthar.

94. Fourteen months after acquiring Synacthen, Mallinckrodt acquired Questcor for \$5.9 billion. The vast majority of Questcor's value was attributable to Acthar and Synacthen.

95. However, despite its claims, Mallinckrodt has not brought Synacthen to market for any indication. Instead, it keeps Synacthen off the market to protect its monopoly power and high prices for Acthar.

Acthar Is Not as Efficacious as Mallinckrodt Claims in its Marketing

96. The drug Mallinckrodt has been selling has not always been the drug described on the Acthar label or the drug Mallinckrodt has been marketing to physicians and patients for the treatment of IS and other ailments. Further, the drug has not contained all of the active ingredients it says it does. As a result, the product being sold is not the product that its label or its marketing says is being sold. This constitutes a consumer fraud in many respects.

97. When a pharmaceutical drug company submits a drug for FDA approval, it also submits a label, setting forth the active ingredients, among other things. Once the FDA approves the drug and the label, the company must sell the drug described on the label.

98. CEO Don Bailey claimed publically in August 2011 that while "Acthar is an extraction of porcine pituitaries", "it's an undisclosed composition, so that's a trade secret." He also claimed that it is a barrier to entry for competitors to enter the market for ACTH drugs that "there are probably multiple active ingredients" in Acthar, and "there are multiple peptides within Acthar, and they're undisclosed."

99. Apart from the fact that a drug approved by the FDA must describe all active ingredients contained in the medicine, which Mallinckrodt's CEO Bailey stated Acthar does not, Acthar's Package Insert states that it contains a certain concentration of its active ingredient.

100. Acthar's label states that it contains porcine ACTH (adrenocorticotrophic hormone). Thus, the one active ingredient, explicit in the drug's label, is corticotropin, or purified ACTH.

101. Porcine ACTH is defined by a particular 39 amino acid sequence which is differentiated from human ACTH only as to the peptide in the 31st position. That makes it a potentially effective precursor to human ACTH, which provides its efficacy (to the extent that efficacy is understood).

102. Prior to 1972, it was believed the 30th amino acid in the porcine ACTH sequence was Glutamine (Gln). However, this was found to be incorrect.

103. In 1972, it was discovered that the 30th amino acid in ACTH was actually Glutamic acid (Glu). Glutamic acid can be created by the hydrolysis (or deamidation) of Glutamine (specifically: Gln + H₂O = Glu + NH₂). In the case of ACTH, however, the amino acid in the 30th position is already deamidated – that is, the presence of Glu (+NH₂) instead of Gln in the 30th position does not mean ACTH is deamidated. Instead, it was discovered that all porcine ACTH – deamidated or otherwise – has Glu in the 30th position.

104. What delineates porcine ACTH from deamidated porcine ACTH is a change in the 25th amino acid in the sequence, Asparagine (Asn). Deamidated ACTH has, as a result of hydrolysis, aspartic acid (Asp) in the 25th spot.

105. The Acthar Package Inserts have consistently shown a "Description" with Gln – not Glu -- in the 30th amino acid position, and Asp in the 25th amino acid position. *Compare* Acthar Package Insert, Issued 09/2012 ("2012 Package Insert"), at page 4 of 4 (at Exhibit "D" hereto) with Acthar Package Insert, Revised 01/2015 ("2015 Package Insert"), at page 12 of 16 (at Exhibit "E" hereto).

106. This appears to reflect the fact that the sellers of Acthar never bothered to correct the erroneous, historical sequence for non-deamidated corticotropin. In other words, Acthar's current label is the same as it was before 1972, despite a change in the scientific understanding about how the amino acid sequence in ACTH actually functioned. Questcor did not seek such change in 2001 when it acquired Acthar from Aventis, and Mallinckrodt has not changed the label since acquiring Questcor.

107. The graphic in the Acthar Package Inserts also have remained the same. They appear to consistently reflect the peptide sequence of ACTH as it was understood prior to 1972. In other words, neither Questcor nor Mallinckrodt have ever sought to tell the consuming public what it knows to be true – that the active ingredient in Acthar, corticotrophin, is in fact deamidated corticotrophin.

108. The official USP monograph for Acthar identifies repository corticotropin injection as “corticotropin in a solution of partially hydrolyzed gelatin. Its potency is not less than 80.0 percent and not more than 125.0 percent of the potency stated on the label. Therefore, to comply with the USP monograph, Acthar must contain between 80% (64 USP units of corticotropin per ml) and 125% (100 USP units of corticotropin per ml).

109. The Acthar label states that it contains “80 USP units per ml.” *Compare* 2012 Label (Ex. D) at 1 of 4, *with* 2015 Label (Ex. E) at 1, 5 of 12.

110. Independent testing conducted in 2014 found that Acthar being sold by Questcor was deficient in relation to the product described on its label in several respects.

111. In February 2014, Citron Research published a report titled, “The Untold Secret that Questcor has been Covering Up” Acthar Faces Severe Risk of Being Pulled off the Market by the FDA.” In a preface to the report titled, “What Led Us to this Study”, Citron quotes the

same statements of CEO Don Bailey made in August 2011 (quoted above).

112. Citron tested several units of Acthar and found they contained deamidated porcine ACTH/corticotropin. They also found that Acthar contains less corticotropin, deamidated or otherwise, than is asserted on Acthar's label. Thus, Citron identified several problems relating to the Acthar product being sold, in relation to what is described on Acthar's label.

113. Principally, the Acthar being sold contains deamidated corticotropin at high enough concentrations as to dilute the potency, and therefore the effectiveness, of the active corticotrophin to below the level stated on either the label or the USP monograph.

114. Since deamidation changes the protein function, reducing its potency, the quality and effectiveness of the product is reduced. Mallinckrodt never disclosed the actual levels of the active ingredient in the Acthar being sold, or the potency of such product.

115. This can cause serious health concerns as the dosage levels recommended are set based upon by the potency of the medicine, especially in the vulnerable population of the infant patients being prescribed Acthar to treat IS.

116. In response to Citron's findings, in March 2014, Questcor filed an 8-K with the SEC. *See Exhibit "F" hereto.* The 8-K included the following statement:

Following Questcor's 2001 acquisition of Acthar from Aventis, the FDA reviewed and approved the transfer of the manufacturing process, final formulation and fill process, release specifications and bioassays required for testing and release of Acthar Active Pharmaceutical Ingredient, or API, and Acthar finished vials. Acthar manufacturing processes and specifications have remained unchanged since these approvals were granted. Based on FDA-approved testing requirements, each lot of Acthar meets FDA-mandated specifications, for potency, which have not changed over several decades.

Regarding Acthar containing "deamidated corticotrophin", this peptide has been listed for many years in the FDA-approved Acthar package inserts. The amino acid sequence for "ACTH" provided in

the Description section of the current FDA-approved Acthar package insert and the FDA-approved package inserts before and after Questcor's 2001 acquisition of Acthar is, in fact porcine deamidated ACTH(1-39) or what has been referred to by others as "deamidated corticotrophin." Therefore, what [Citron] claims to have found appears to be consistent with what is specified on the FDA-approved Acthar package insert.

Acthar is a naturally-derived, complex peptide formulation that is not yet fully understood. This is not unusual for naturally-derived products. As the FDA notes on its website, "In contrast to chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized, biological products are generally derived from living material – human, animal, or microorganism -- are complex in structure, and thus are usually not fully characterized.

March 3, 2014 Questcor Form 8-K at Item 7.01 (Ex. F)(bracketed text added).

117. Consequently, in response to Citron's findings, Questcor *admitted* that the Acthar it sells contains deamidated ACTH. However, the Package Inserts Mallinckrodt continues to supply with its product continue to state the product being sold is porcine ACTH, not deamidated porcine ACTH.

118. Questcor sought to excuse its deliberate sale of a product not of the quality, character and condition of that which the company markets and sells by claiming "Acthar is a naturally-derived, complex peptide formulation that is not yet fully understood." It cited in support a "contrast" noted by the FDA between "chemically synthesized small molecular weight drugs, which have a well-defined structure and can be thoroughly characterized," and "biological products [which] are generally derived from living material – human, animal, or microorganism – [and which] are complex in structure, and thus are usually not fully characterized."

119. But Acthar is a drug, not a biologic. Acthar was able to achieve "orphan drug" status because it is a drug.

120. By Mallinckrodt's CEO admitting the company does not know exactly what is in

Acthar, that the drug being sold is actually deamidated [ie., decreased potency and effectiveness], and that the drug actually, probably contains other active ingredients which are secret, undisclosed, and themselves not widely understood, Mallinckrodt's sales of Acthar contravene several sections of the consumer fraud laws set forth more fully below.

121. Mallinckrodt sought to avoid the impact of the Citron report and findings by claiming they were sponsored by investors engaging in a "short attack against the Company and its stock price." But, the findings are what they are, have not been refuted by the company, and in fact have been admitted in large part by the company.

122. Furthermore, in April 2015, Mallinckrodt settled a securities fraud class action brought against it by its investors against the company in January 2013 in the United States District Court for the Central District of California for the sum of \$38 million. The securities lawsuit charged the company with, *inter alia*, "issu(ing) false and misleading statements about the effectiveness of, and prospects for, Questcor's sole product, Acthar." The court denied in part the Defendants' motions to dismiss, allowing certain claims to proceed. The court granted class certification in November 2014.

123. Following the settlement, Mallinckrodt's CEO, Mark Trudeau, suggested to investors on October 6, 2015, that drug prices "should be reflective of the value that you deliver to the marketplace." However, while "Acthar [may be] a very complex product, a naturally-derived mixture of organic components", it does not appear to contain what Mallinckrodt claims it contains. In other words, the "value" Mallinckrodt ascribes to Acthar does not warrant the sort of price inflation and gouging displayed by the company since 2007.

CLASS ACTION ALLEGATIONS

124. The City of Rockford brings this action pursuant to Rule 23(a), (b)(2) and (b)(3)

of the Federal Rules of Civil Procedure, on behalf of itself and other similarly-situated entities in Illinois and throughout the country pursuant to Rule 23 of the Federal Rules of Civil Procedure, the following proposed Class:

All self-funded entities in the United States and its Territories that paid for Acthar from August 2007 through the present.

Excluded from the above Class are: (a) Defendants and any entity in which Defendants have a controlling interest, and their legal representatives, offices, directors, assignees and successors, and (b) any co-conspirators.

Numerosity

125. The proposed Class consists of potentially hundreds of non-Medicaid public payors in the proposed Class located throughout Illinois and the United States, based on the fact that Mallinckrodt has sold thousands of vials of Acthar in each quarter over the last few years alone. Thus, the Class is so numerous that joinder of all of its members is impractical.

126. Despite the size of the Class, its members are easily identifiable, as each patient was required by Defendants to fill out an Acthar Start Form (Exhibit "A" hereto) which forms were returned to, and have been maintained by, Defendants. As a result, it is believed that the records needed to identify the members of the Class are in the hands of UBC and/or Mallinckrodt.

Typicality

127. The City's claims are typical of the claims of the Class, in that the representative Plaintiff is an entity who, like Class Members, purchased Acthar at unlawful prices due to the unlawful conduct of the Defendants. The City, like all Class members, has been damaged and has sustained economic injuries in the form of overcharges by the misconduct of the Defendants, because it paid higher prices than it would have paid absent Defendants' improper actions.

Adequacy of Representation

128. The City can and will fairly and adequately represent and protect the interests of the Class. Plaintiff has no interest that conflicts with or is antagonistic to the interests of the Class.

129. The City is represented by counsel who are experienced and competent in the prosecution of complex actions, including antitrust and consumer fraud class actions.

Commonality

130. The factual and legal bases for the Defendants' misconduct are common to Class members and represent a common thread of antitrust racketeering and consumer fraud resulting in injury to Plaintiff and the Class. Common questions of law and fact in this case include, but are not limited to, the following:

- a. whether Mallinckrodt and its agents unlawfully impaired or impeded competition in the market for ACTH drugs;
- b. whether Mallinckrodt and its agents established a monopoly in the market for ACTH drugs;
- c. whether Mallinckrodt and its agents engaged in anticompetitive conduct in order to disadvantage its competitors and maintain monopoly power in the market for ACTH drugs;
- d. whether Mallinckrodt exercised monopoly power with respect to Acthar;
- e. the effects of Mallinckrodt's anticompetitive conduct on Acthar prices;
- f. whether Mallinckrodt formed an enterprise with UBC and/or other agents for the purpose of carrying out the ASAP scheme;
- g. whether Defendants used the U.S. mails and interstate wire facilities to carry out an unfair ASAP scheme;
- h. whether the Defendants engaged in a unfair and deceptive scheme of improperly inflating the prices of Acthar paid by Plaintiff and the Class;
- i. whether the Defendants artificially inflated the prices of Acthar;

- j. whether Plaintiff and the Class have been overcharged and thus damaged by paying artificially inflated prices for Acthar as a result of the unlawful behavior of Mallinckrodt and its agents;
- k. whether the Defendants are liable to Plaintiff and the Class for statutory damages for conduct actionable under the Illinois Consumer Fraud and Deceptive Practices Act, and the consumer protection laws of other states;
- l. whether the Defendants have been unjustly enriched by their unlawful conduct;
- m. whether the Defendants engaged in a conspiracy and/or concerted conduct in deceiving Plaintiff and the Class about Acthar and Acthar pricing, and concealing the truth about their unlawful conduct in artificially inflating the prices of Acthar;
- n. whether Plaintiff and members of the Class are entitled to declaratory and injunctive relief as to Defendants' conduct;
- o. whether Plaintiff and the members of the Class are entitled to damages, and, if so, the nature of such damages;
- p. the proper measure of damages; and
- q. whether Plaintiff and members of the Class are entitled to an award of punitive damages, reasonable attorneys' fees, prejudgment interest, post-judgment interest, costs of suit, and other appropriate relief under the circumstances of this case.

Predominance

131. These questions of law and fact common to the members of the Class predominate over questions, if any, that may affect only individual members because Mallinckrodt and its agents have acted and refused to act on grounds generally applicable to the entire Class. Such generally applicable conduct is inherent in Mallinckrodt's exclusionary and anticompetitive conduct in monopolizing and attempting to monopolize the ACTH drug market, and other conduct as more fully alleged herein.

Superiority

132. A class action is superior to any other available method for the fair and efficient adjudication of this controversy in that, among other things, such treatment will permit a large number of similarly situated governmental entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of effort and expense that numerous individual actions would engender.

133. The prosecution of separate actions by individual members of the Plaintiff Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class. These adjudications would establish incompatible standards of conduct for the Defendants which would, as a practical matter, be disparities of the claims of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests.

134. The Defendants have acted or refused to act on grounds generally applicable to all members of the Class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the Class as a whole.

135. Accordingly, class certification is appropriate under Rule 23(b)(1)(A), 23(b)(1)(B), 23(b)(2) and 23(b)(3).

COUNT I
CITY OF ROCKFORD v. MALLINCKRODT
MONOPOLIZATION OF THE ACTH DRUG MARKET
(15 U.S.C. § 2)

136. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein.

137. Defendants have, and at all relevant times had, monopoly power in the market for the sale of ACTH drugs in the United States.

138. Mallinckrodt has willfully maintained its monopoly power in the ACTH drug market. As described more fully above, in 2007, Mallinckrodt leveraged and enhanced its monopoly power by limiting the distribution of its sole specialty drug to just one specialty pharmacy distributor, and employing an exclusive agent, UBC, to coordinate all aspects of its distribution and sales of its product, from prescription by the physician, to delivery to the patient, to reimbursement by the payor. This allowed Mallinckrodt to raise its prices tenfold initially, and nearly double in the ensuing years.

139. Then, in 2013, when faced with a competitive threat to its monopoly, Mallinckrodt disrupted the bidding process for Synacthen by intervening at the last minute to pay multiple times what had been offered by three competitors. It licensed the U.S. rights to Synacthen from Novartis, not to bring this viable synthetic alternative to market, but to eliminate the nascent competitive threat posed by an independently owned Synacthen.

140. Such conduct reasonably contributed to Mallinckrodt's maintenance of monopoly power. The purpose and effect of such conduct has been to suppress rather than promote competition on the merits.

141. Mallinckrodt used this monopoly power to inflate the price of Acthar from \$40 per vial to over \$35,000.00 per vial in recent years. This represents a more than 88,000% increase over the course of Mallinckrodt's ownership of this product.

142. The challenged conduct caused Plaintiff and the Class to pay artificially inflated prices for Acthar in the ACTH drug market.

143. There is no procompetitive justification for the conduct of Mallinckrodt and its exclusive agents.

144. The City of Rockford has been injured in its business and property by reason of

Mallinckrodt's unlawful monopolization. Plaintiff's injuries consist of paying higher prices to purchase Acthar than it would have paid absent the conduct of Mallinckrodt and its exclusive agents. Plaintiff's injuries are the type of harm the antitrust laws were designed to prevent and flow from that which makes Mallinckrodt's conduct unlawful.

145. Defendants' acts and practices constitute monopolization in violation of Section 2 of the Sherman Act, 15 U.S.C. § 2.

COUNT II
CITY OF ROCKFORD v. DEFENDANTS
ANTI-COMPETITIVE AGREEMENTS IN UNREASONABLE
RESTRAINT OF TRADE (15 U.S.C. § 1)

146. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

147. As set forth above, Mallinckrodt has entered into exclusive agreements with its competitor, Novartis, its agent, UBC, and its exclusive specialty pharmacy distributor, Curascript, to preserve and extend its monopoly power and to allow it to maintain and extend its high prices for Acthar.

148. There was no legitimate business justification on the part of Mallinckrodt for these exclusive and exclusionary agreements, and these agreements: (a) substantially foreclosed and excluded competition from other potential ACTH manufacturers and distributors, and (b) resulted in Mallinckrodt's willful maintenance and unlawful exercise of monopoly power in the market for ACTH drugs.

149. At all relevant times, Mallinckrodt's exclusive and exclusionary agreements with UBC and other agents assisted Mallinckrodt in: (a) effectively excluding less expensive, potentially superior competitive products from the ACTH drug market; (b) maintaining Mallinckrodt's dominant market share and monopoly power in the ACTH drug market; (c)

maintaining prices at artificially high levels for Acthar; and (d) otherwise reaping the benefits of its illegal monopoly power.

150. There is no procompetitive justification for Mallinckrodt's conduct.

151. Plaintiff has been injured in its business and property by reason of the alleged collusion and conspiracy between Mallinckrodt and its competitor, its exclusive agent, and its exclusive specialty distributor, which facilitated, enabled, assisted, and furthered Mallinckrodt's substantial foreclosure and exclusion of competition and monopolization of the ACTH drug market.

152. Plaintiff's injuries consist of paying higher prices to purchase Acthar than it would have paid absent Mallinckrodt's unlawful conduct. Plaintiff's injuries are the type the antitrust laws were designed to prevent and flow from that which makes Mallinckrodt's conduct unlawful.

153. Defendants' acts and practices constitute anti-competitive agreements in unreasonable restraint of trade in violation of Section 1 of the Sherman Act, 15 U.S.C. §1.

COUNT III
CITY OF ROCKFORD v. DEFENDANTS
Violation of 18 U.S.C. § 1962(c)

154. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

155. Defendants are each "persons" within the meaning of 18 U.S.C. § 1961(3), who each conducted the affairs of an association in fact enterprise affecting interstate commerce through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(c). Plaintiff and the members of the Class are also persons.

156. At all relevant times, in violation of 18 U.S.C. § 1962(c), Mallinckrodt, UBC and

other co-conspirators conducted the affairs of an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4) consisting of Mallinckrodt, UBC, and CuraScript, including their directors, employees, and agents, which is manifested in the ASAP program (the “ASAP Enterprise”).

157. The ASAP Enterprise was begun in 2007 and is an ongoing and continuing business organization consisting of both corporations and individuals associated for the common purpose of distributing, marketing, selling, purchasing, and administering Acthar to plaintiff and the Class, and deriving substantial profits from these activities.

158. The ASAP Enterprise engages in and affects interstate commerce because it engages in the following activities across state boundaries: the manufacture, distribution, marketing, sale, and/or purchase of Acthar, the transmission of ASAP program literature (including the Acthar Start Form at Exhibit “A” hereto), the operating of the ASAP program website, and the transmission and/or the receipt of invoices and payments related to the prescription and use of Acthar. Through these activities the ASAP Enterprise distributes Acthar to thousands of individual patients, including those receiving prescription drug benefits from the City of Rockford and the Class.

159. The ASAP Enterprise functioned as a continuing unit as evidenced by the continuing coordination of activities between Mallinckrodt and UBC. There is a common communication network by which Mallinckrodt and UBC (and other agents, including Curascript) shared and continue to share information on a regular basis for all times relevant to this lawsuit, but beginning at least in 2007 and continuing through the present. Typically, this communication occurred by use of the wires and mails, in which Mallinckrodt, UBC and Curascript all agree to charge inflated prices for Acthar to the infant children of City employees

and other Class members. These entities functioned as a continuing unit for the purposes of implementing the scheme to inflate the prices of Acthar by and through ASAP. When issues arose during the scheme, each agreed to take actions to hide the scheme and to continue its existence.

160. Defendants have exerted control over the ASAP Enterprise, have associations with the Enterprise, and have directly or indirectly conducted or participated in the conduct of the affairs of the ASAP Enterprise in the following ways:

- a. Defendants have directly controlled the price at which Plaintiff and the Class purchase Acthar;
- b. Defendants have directly controlled the price at which Plaintiff and the Class reimburse for Acthar;
- c. Defendants have directly controlled the ASAP program materials and website which enroll patients in an exclusive distribution network for the administration of Acthar, allowing Mallinckrodt to conduct its unconscionable and unfair pricing of Acthar;
- d. Defendants have directly controlled the exclusive distribution network for Acthar through the ASAP Enterprise;
- e. Defendants have relied on their employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires; and
- f. Defendants have participated in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices.

161. Defendants have conducted and participated in the affairs of the ASAP Enterprise through a pattern of racketeering activity that includes acts indictable under 18 U.S.C. § 1341, relating to mail fraud, and 18 U.S.C. § 1345, relating to wire fraud. Defendants' pattern of racketeering activity likely involved hundreds, if not thousands, of separate instances of the use of the United States mail, private shipping services, facsimiles, or interstate wires, including the internet, in furtherance of its fraudulent and unlawful scheme. Each of these fraudulent mailing

and interstate wire transmissions separately constitutes a “racketeering activity” within the meaning of 18 U.S.C. § 1961(1). Collectively, these violations constitute a “pattern of racketeering activity” within the meaning of 18 U.S.C. § 1961(5) in which the Defendants intended to defraud Plaintiff and members of the Class.

162. As described in greater detail herein, Defendants’ fraudulent scheme consisted of confining patients to an exclusive distribution network, such that they could drastically inflate the prices charged for Acthar. By conducting this program through the mail and wires, Defendants engaged in a repeated, fraudulent, and unlawful course of conduct constituting a pattern of racketeering.

163. These racketeering activities amounted to a continuing course of conduct, with similar pattern and purpose, intended to harm Plaintiff and the Class. Each instance of racketeering activity perpetuated by the Defendants was related, and had a similar intended purpose, involved similar participants and methods of execution, and have the same results affecting the same class of victims, including Plaintiff and the Class. Defendants had engaged in this pattern of racketeering activity for the purpose of conducting the ongoing business affairs of the ASAP Enterprise.

164. Defendants’ violations and pattern of racketeering activity had directly and proximately cause Plaintiff and members of the Class to be injured in their property insofar as Plaintiff and members of the Class have paid thousands of dollars in inflated reimbursements and other payments for Acthar.

165. By virtue of these violations of 18 U.S.C. § 1962(c), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorneys fees.

COUNT IV
CITY OF ROCKFORD v. DEFENDANTS
Violation of 18 U.S.C. § 1962(a)

166. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further allege as follows:

167. Throughout the Class Period, Defendants have violated the RICO statute by using and investing income that was derived from a pattern of racketeering activity as described herein. This income was used to acquire, establish, and/or operate the ASAP Enterprise in and affecting interstate commerce.

168. The enterprise at issue is an association-in-fact within the meaning of 18 U.S.C. § 1961(4) consisting of Mallinckrodt, UBC, and CuraScript, including their directors, employees, and agents, which is manifested in the ASAP program (“ASAP Enterprise”). The ASAP Enterprise is an ongoing and continuing business organization consisting of both corporations and individuals associated for the common purpose of selling, purchasing, and administering Acthar to Plaintiff and their individual participants, and deriving profits from these activities.

169. Defendants engaged in a pattern of racketeering activity described in greater detail herein.

170. Plaintiff and members of the Class have been directly and proximately injured in their property by the Defendants’ use and investment of the racketeering income in the acquisition, establishment, and operation of the ASAP Enterprise. The injury to Plaintiff and the Class’s businesses or property stemming from these violations has been realized by the over-payment for Acthar.

171. The use and investment of racketeering income by the Defendants directly and proximately injured the Plaintiff and the Class in a manner than was distinct from the injury

caused by the pattern of racketeering activity described herein.

172. By virtue of these violations of 18 U.S.C. § 1962(a), Defendants are jointly and severally liable to Plaintiff and the Class for three times the damages Plaintiff and the Class have sustained, plus the costs of this suit, including reasonable attorneys fees.

COUNT V
CITY OF ROCKFORD v. DEFENDANTS
(18 U.S.C. § 1962(D))

173. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

174. Mallinckrodt violated 18 USC § 1962(d) by conspiring to associate with a racketeering enterprise, in violation of 18 U.S.C. § 1962(c). Mallinckrodt knowingly joined UBC and others in a conspiracy to inflate the prices of Acthar in violation of § 1962(c).

175. That Mallinckrodt knew and adopted the criminal purpose of the Enterprise is evident from its own documents and public statements of its officers. Mallinckrodt communications reflect an express illegal agreement between Mallinckrodt and Curascript to limit the distribution of Acthar in order. Mallinckrodt's officers have stated it was this agreement in 2007 that was the hallmark of a new strategy to increase revenues and profits.

176. Additionally, Mallinckrodt's conduct in sending e-mails, faxes and other communications to UBC to direct the distribution and sale of Acthar through ASAP is consistent with the existence of an agreement to carry out the scheme to inflate prices and maximize profits.

177. Mallinckrodt actively furthered the goals of the ASAP Enterprise to defraud end payors, like the City. It changed its distribution scheme on Acthr with the intention that the changes would affect the prices of Acthar; engaged in frequent discussions with UBC and Curascript about is plan to raise Acthar prices in the marketplace; made requests that UBC and

Curascript change the Acthar prices charged n conjunction with its price increases; and publicly boasted about the effects of the scheme without disclosing its details.

178. Plaintiff and other members of the Class have been injured in their business or property because they have paid thousands of dollars in overpayments that they would not have made had Defendants not conspired to engage in racketeering activity.

179. As a co-conspirator, Mallinckrodt is jointly and severally liable for all damage that occurred as a result of both its actions and that of UBC in furtherance of the conspiracy to raise prices of Acthar. Mallinckrodt is liable for all damages arising from UBC's conduct in furtherance of the scheme.

180. Under the provisions of Section 1964(c) of RICO, Mallinckrodt is jointly and severally liable to Plaintiff for three times the damages that Plaintiff has sustained, plus the costs of bringing this suit, including reasonable attorneys' fees.

COUNT VI
CITY OF ROCKFORD v. DEFENDANTS
VIOLATION OF ILLINOIS CONSUMER FRAUD
AND DECEPTIVE PRACTICES ACT
(815 ILCS 505/1 et. seq.)

181. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein and further allege as follows.

182. The Defendants have violated the Illinois Consumer Fraud and Deceptive Practices Act ("CFA"), 815 ILCS 505/1, et seq., by their actions as more fully described herein.

183. Rockford is empowered to bring this action on behalf of itself and other "persons" who have purchased or reimbursed Acthar at inflated prices and, as a result, have suffered, are suffering, and will continue to suffer economic harm as a result of the Defendants' actions.

184. Under the CFA, a "person" includes, but is not limited to, a natural person or his

legal representative, partnership, corporation (domestic and foreign), company, trust, business entity or association, and any agent, employee, salesman, partner, officer, director, member, stockholder, associate, trustee or cestui que trust thereof. See 815 ILCS 505/1(c).

185. Plaintiff and the other Illinois-based members of the Class are persons under the CFA.

186. Plaintiff has standing to bring this claim in that Rockford is both end payor and purchaser/reimburser of Acthar. Rockford performs these functions for both personal and business purposes, and in its representative capacity on behalf of, and for the benefit of, its employees who, in turn, make use of the Acthar prescribed primarily for personal, family and/or household purposes.

187. In distributing, pricing, marketing and selling Acthar to employees of the City of Rockford, and to the other Illinois members of the Class, and in engaging in the unlawful conduct more fully described herein, the Defendants are engaging in trade or commerce that directly or indirectly harmed consumers in Illinois within the meaning of 815 ILCS 505/1(f).

188. Specifically, by engaging in the acts and practices set forth above, the Defendants' conduct constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 815 ILCS 505/2 and the Uniform Deceptive Trade Practices Act, 815 ILCS 510/2, including, but not limited to, the following:

- a. Passing off goods or services as those of another, within the meaning of 815 ILCS 510/2(a)(1);
- b. causing likelihood of confusion or misunderstanding as to the source, sponsorship, approval or certification of goods or service, within the meaning of 815 ILCS 510/2(a)(2);
- c. causing likelihood of confusion or of misunderstanding as to affiliation, connection or association with, or certification by another, within the meaning of 815 ILCS 510/2(a)(3);

- d. representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation or connection that he does not have within the meaning of 815 ILCS 510/2(a)(5);
- e. representing that goods or services are of a particular standard, quality or grade, or that goods are of a particular style or model, if they are of another, within the meaning 815 ILCS 510/2(a)(7);
- f. advertising goods or services with the intent not to sell them as advertised within the meaning of 815 ILCS 510/2(a)(9);
- g. engaging in any other fraudulent or deceptive conduct which creates a likelihood of confusion or misunderstanding within the meaning of 815 ILCS 510/2(a)(12).

189. Defendants willfully engaged in such practices knowing them to be unfair and deceptive and with the intent that Plaintiff and the Class would rely on and pay the exorbitant prices Defendants charged for Acthar to their detriment.

190. Defendants violated the CFA and caused harm to Plaintiff and the Class each time they raised the prices charged to Plaintiff and the Class for this essential medication.

191. Plaintiff and its employees, as well as the members of the Class, to whom Acthar was prescribed reasonably relied upon Defendants' direct representations concerning, among other things, the appropriateness of Acthar to treat their indicated conditions and the appropriateness of the prices charged for Acthar to their detriment.

192. Defendants' conduct as more fully described herein constitutes unfair methods of competition and unfair or deceptive acts or practices within the meaning of 815 ILCS 510/2, including, but not limited to, engaging in any other deceptive conduct which creates a likelihood of confusion or of misunderstanding, within the meaning of 815 ILCS 510/2(a)(12).

193. Defendants' conduct more fully described herein is proscribed and unlawful

pursuant 815 ILCS 505/2, 815 ILCS 505/9, 815 ILCS 505/10a.

194. Defendants are liable for their actions, and are jointly and severally liable for the actions of their co-conspirators, for each of these violations as independent, unfair and deceptive acts in violation of the CFA, and for their course of conduct comprising an unfair and deceptive act or practice in violation of the CFA.

195. As a result of the Defendants' unfair and deceptive acts and practices, Plaintiff and the Class have and will continue to suffer ascertainable losses and damages in an amount to be determined at trial, which amounts should be awarded pursuant to 815 ILCS 505/9-10a. These amounts should be trebled, in this Court's discretion, as appropriate.

COUNT VII
CITY OF ROCKFORD v. DEFENDANTS
UNJUST ENRICHMENT

196. Plaintiff hereby incorporates by reference the averments of the foregoing paragraphs as if fully set forth herein and further alleges as follows:

197. By engaging in the conduct described in this Complaint, the Defendants have knowingly obtained benefits from Plaintiff and the Class, namely grossly inflated revenue from the sales of Acthar, under circumstances such that it would be inequitable and unjust for these Defendants to retain them.

198. By engaging in the antitrust conduct and other unlawful conduct described herein, the Defendants have been knowingly enriched by the amount charged for Acthar over and above what they could have charged in a competitive market, and what was charged previously before the unlawful conduct was undertaken. By establishing and maintain a monopoly, exercising monopoly power, and engaging in other unlawful acts and practices, the Defendants were able to extract exorbitant revenue from consumers that had nowhere else to turn for treatment. This

conduct violated United States antitrust laws, RICO and state consumer fraud laws, and, as such, interfered with the legally protected interests of Plaintiff and the Class.

199. Plaintiff and each member of the Class are therefore entitled to an award of compensatory damages in an amount to be determined at trial, or the imposition of a constructive trust upon the monies derived by the Defendants by means of the above-described actions.

COUNT VIII
**CITY OF ROCKFORD v. MALLINCKRODT, UBC,
AND UNNAMED CO-CONSPIRATOR DEFENDANTS**
CONSPIRACY

200. Plaintiff hereby incorporates by reference the preceding and following paragraphs hereof as if fully set forth herein.

201. As set forth more fully above, beginning at least as early as 2007, the exact date being unknown to the Plaintiff, and continuing thereafter until the present, Defendants Mallinckrodt, UBC, and unnamed co-conspirators, between and among themselves and others, entered into an agreement and/or otherwise engaged in a continuing conspiracy to deceive the Plaintiff by causing them to pay more for Acthar than they otherwise would have paid in the absence of the Defendants' conspiracy.

202. Pursuant to the unfair and deceptive scheme to distribute, market, sell, purchase, and administer Acthar to derive substantial profits, and the conspiracy alleged herein, and in furtherance thereof, Defendants, including Mallinckrodt, UBC, and their co-conspirators engaged in a wide range of activities, the purpose and effect of which was to deceive Plaintiff, and acted or took substantial steps in furtherance of the conspiracy. Those acts include the following:

- a. discussing and agreeing among themselves and with their co-conspirators that they would increase and directly control the price at which Plaintiff and the Class purchased Acthar;

- b. discussing and agreeing among themselves and with their co-conspirators that they would directly control the price at which Plaintiff and the Class reimbursed for Acthar;
- c. discussing and agreeing among themselves and with their co-conspirators that they would directly control the ASAP program materials and website which market enrollment of patients into an exclusive distribution network for the administration of Acthar, which allows Mallinckrodt to conduct its unconscionable and unfair pricing of Acthar;
- d. discussing and agreeing among themselves and with their co-conspirators that they would directly control the exclusive distribution network for Acthar through the ASAP Enterprise;
- e. discussing and agreeing among themselves and with their co-conspirators that they would rely on employees to promote the ASAP program through the marketing alleged herein, through the mail and the wires; and
- f. discussing and agreeing among themselves and with their co-conspirators that they would participate in the affairs of the ASAP Enterprise by using a fraudulent scheme to market and sell Acthar at inflated prices.
- g. discussing and agreeing among themselves and with their co-conspirators that they would conceal and suppress the truth about the Acthar inflated prices and price gouging, and the monies earned from payors, like Plaintiff and the Class, from such unlawful as conduct alleged herein.

203. In addition to the specific facts set forth above, upon information and belief, the Defendants, including Mallinckrodt, UBC, and their co-conspirators, engaged in conspiratorial meetings, among the purposes of which meetings were to discuss the importance of controlling the distributing, marketing, selling, purchasing, and administering of Acthar to Plaintiff and the Class, and deriving substantial profits from these activities.

204. Conspiratorial meetings, conferences, telephone and other communications were held between and among the Defendants, including Mallinckrodt, UBC, and their co-conspirators, for the purpose of discussing the improper sales and marketing practices set forth herein, and the concealment of the truth alleged herein.

205. The Defendants performed the conspiratorial acts set forth herein intending to

injure reimbursers and payors of Acthar, including Plaintiff and the Class, by causing them to pay inflated prices so that the Defendants could derive substantial profits.

206. The Defendants performed the acts alleged herein in furtherance of the common plan or design for the conspiracy with intent and/or with knowledge of the injury and damage it would cause to the Plaintiff and the Class, and with knowledge and intent to cause such injuries and/or with reckless disregard for the consequences.

207. As a direct and proximate result of the Defendants' conspiracy as alleged herein, Plaintiff and the Class have been injured and damaged, and the Defendants are jointly and severally liable for such injuries and damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff and the Class request the Court to enter the following relief:

- a. Certify this case as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure, and denominate Plaintiff as an adequate representative for the Class and their undersigned counsel as counsel for the Class;
- b. Declare unlawful the acts and practices alleged herein, enjoin the Defendants from committing the acts alleged herein, and restore the status quo before the unlawful conduct took place;
- c. Enter judgment against all Defendants for the violations alleged herein;
- d. Award the actual damages incurred by Plaintiff and the members of the Class as a result of the wrongful acts complained of, along with pre-judgment and post-judgment interest at the maximum rate allowed by law;
- e. Award statutory damages set forth herein under the statutory claims alleged;

- f. Award of treble damages or multiple damages by operation of law;
- g. Award punitive damages;
- h. Award Plaintiff the costs of this action, including reasonable attorney's fees, and, where applicable, expert fees; and
- i. Award such other and further relief as the Court may deem just and appropriate.

JURY DEMAND

Plaintiff and the Class demand a trial by jury of all issues so triable in this cause.

Respectfully submitted,

The City of Rockford

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